K122292

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OCT 24 2012

510(k) Summary

Reliance Medical Systems, LLC
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Contact: Bret M. Berry
Member-Manager

08 October 2012

Common or Usual Name:	Spinal Fixation Device
Proposed Proprietary or Trade Name:	Reliance Posterior Cervical-Thoracic System
Classification Name:	Spinal Interlaminal Fixation Orthosis (per 21 CFR 888.3050)
Product Code:	KWP, MNH, MNI

Substantial Equivalence

The **Reliance Posterior Cervical-Thoracic System** is substantially equivalent to the legally marketed Medtronic Vertex Reconstruction System (K003780), Pioneer Surgical Posterior Cervical Thoracic System (K092295), the Theken Atoll Cervico-Thoracic System (K083073), and the Alphatec Solanas Posterior Stabilization System (K052201). The **Reliance Posterior Cervical-Thoracic System** is equivalent to these commercially available devices in terms of material, intended use, levels of attachment, size range, and strength.

Device Description

The **Reliance Posterior Cervical-Thoracic System** contains posterior spinal attachment elements in a variety of configurations based upon rod diameter. These include a Titanium alloy based Ø3.5mm rod configuration, a Titanium alloy based Ø4.0mm rod configuration and a Titanium alloy based Ø4.5mm rod configuration. All configurations, regardless of rod size, are available in Ø3.5mm, Ø4.0mm, and Ø4.5mm major screw diameters. These screw diameters are offered in lengths ranging from 10mm to 20mm, with the Ø4.0mm, and Ø4.5mm available up to 50mm. All of these screws are available in both mono-axial and poly-axial options. The poly-axial screws in all of these configurations have an internal taper bushing that circumferentially grasps the rod when the device is locked. Additionally, both the mono-axial and poly-axial screws have a double lead thread.

In addition to the screw sizes mentioned above, reduction-tabbed screws are also available. The reduction-tabbed screws are available in all of the previously mentioned sizes. The **Reliance Posterior Cervical-Thoracic System** also offers a series of crosslink connectors. Furthermore, the **Reliance Posterior Cervical-Thoracic System** includes a series of hooks for attaching to the posterior elements of the cervico-thoracic spine. All of the components discussed above are fabricated from Titanium alloy and should not be used with implants of different materials.

Intended Use/Indications for Use

The **Reliance Posterior Cervical-Thoracic System** is intended to promote fusion of the cervical spine and cervicothoracic junction (C1-T3), and is indicated for the following:

- ddd (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- spondylolisthesis
- spinal stenosis
- fracture/dislocation
- revision of previous cervical spine surgery
- tumors

The use of the polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

Hooks and Rods
The rod and hook components are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.
WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic (T4–T12), or lumbar spine. Pedicle screws are intended for placement only in T1-T3 as a means of anchoring the system.

Performance Data and Substantial Equivalence
The Reliance Posterior Cervical-Thoracic System has undergone Non-Clinical Testing including Static Compressive, Static Torsion, Dynamic Compressive and Dynamic Torsion in accordance with ASTM F1717. The Reliance Posterior Cervical-Thoracic System is substantially equivalent to the predicate devices. Additionally, the Reliance Cervical Plate System is substantially equivalent to the predicate devices in terms of sterilization and biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Reliance Medical Systems, LLC
% Mr. Bret M. Berry
Member-Manager
545 West 500 South, Suite 100
Bountiful, Utah 84010

OCT 24 2012

Re: K122292
Trade/Device Name: Reliance Posterior Cervical-Thoracic System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP, MNH, MNI
Dated: October 09, 2012
Received: October 10, 2012

Dear Mr. Berry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122292

Device Name: Reliance Posterior Cervical-Thoracic System

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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